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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/325,214 06/03/99 NARAHARA

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HM12/0803

MORRISON LAW FIRM
145 NORTH FIFTH AVENUE
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EXAMINER

NGUYEN, B

ART UNIT

PAPER NUMBER

1641

9

DATE MAILED:

08/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/325,214

Applicant(s)
Narahara et al

Examiner
Bao-Thuy L. Nguyen

Group Art Unit
1641



☒ Responsive to communication(s) filed on 6/6/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.

Of the above, claim(s) 1 and 2 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 3-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of group II, claims 3-8 in Paper No. 8 is acknowledged.
2. Claims 1 and 2 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Drawings

3. The drawings are objected to by the draftsman. See the attached form PTO-948 for more information. Correction is required.

Claim Rejections - 35 USC § 112

4. Claims 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 8 are vague and indefinite with respect to the description of the particles and marking elements because it is unclear what these two reagents are and how these two reagents relate to the detectable material. Do they specifically bind the detectable material? Are the marking elements some sort of labeled binding partner?

The recitation of a reaction product being formed and retained in the catching section is confusing because it is unclear if this reaction product only form in the presence of a detectable material, in other words, it is not clear that the marking elements and the particles will not bind to each other in the absence of a detectable material? As such, a complex between the marking elements and the particles alone will provide a false positive test result.

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The recitation of a biological bond between the marking elements and the particles is confusing because it is unclear what is on, or in the particles that can allow for a "biological bond". A bond between a biological material, e.g. a specific binding partner, and an inert particle is not necessarily considered a "biological bond". Please clarify.

The marking elements need to be clearly defined and recited the claim and its binding relationship with the detectable material and particles must be recited to obviate the rejection.

Claim 8 is further confusing because it is unclear how the catching section is related to the other sections. Where is the catching section located with respect to the other section?

The recitation of "marking elements contained in said reaction reagent section", line 25, is confusing because it lacks antecedent support. The reaction reagent section has not been recited as containing particles and marking elements.

Allowable Subject Matter

5. Claims 3-8 are free of the prior art of record.
6. Claims 3-8 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.
7. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach an immunochromatographic device having a detection section comprising a material having a pore size smaller than the size of a reaction product formed between a particle, a binding partner, a label and the analyte of interest. The closest prior art of record, Greenquist (US Patent No. 4,806,311), teach a similar device, however, the detection layer of Greenquist, as with most similar test device, comprises a specific binder to capture and immobilize any reaction products formed between the analyte, the label and any other binding partners. The instant invention lacks a specific binding partner at the detection site, and instead uses filter material of a specific pore size smaller than any reaction product in order to retain and enable the detection thereof.

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8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 3,992,158

US Patent No. 4,469,787

US Patent No. 4,772,550

US Patent No. 4,806,311

US Patent No. 4,859,612

US Patent No. 5,141,850

US Patent No. 5,202,267

US Patent No. 5,236,826

Bangs, L.B., New Developments in particle based tests and immunoassays. Journal of the International Federation of Clinical Chemistry. Vol. 2, No. 4, pp. 188. 1990.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy Nguyen whose telephone number is (703) 308-4243. The examiner can usually be reached Monday through Thursday, from 8:30 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Bao-Thuy Nguyen
Patent Examiner
Group Art Unit 1641
July 20, 2000